AUG 2 1 2002

K022603

## 510(k) Summary of Safety and Effectiveness

*This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.*

| | |
|---|---|
| **Name:**<br>**Address:** | Diagnostic Products Corporation<br>5700 West 96th Street<br>Los Angeles, California 90045-5597 |
| **Telephone Number:**<br>**Facsimile Number:** | (310) 645-8200<br>(310) 645-9999 |
| **Contact Person:** | Edward M. Levine, Ph.D.<br>Director, Clinical Affairs |
| **Date of Preparation:** | August 5, 2002 |
| **Device Name:**<br>**Trade:** | IMMULITE® 1000 |
| **Catalog Number:** | IM1LITE |
| CFR: | A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as microanalysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units. |
| Common: | Discrete photometric chemistry analyzer for clinical use. |
| **Classification**: | Class I device, JJE (21 CFR 862.1260) |
| **Panel:** | Clinical Chemistry |
| **Manufacturer**: | Corporate Headquarters:<br>Diagnostic Products Corp.<br>5700 West 96th Street<br>Los Angeles, CA 90045<br><br>Instrument Manufacturer:<br>DPC Instrument Systems Div.<br>62 Flanders Bartley Road<br>Flanders, NJ 07836<br>(Formally DPC Cirrus Inc.) |

**Establishment Registration Number:** DPC Headquarters Registration Number is 2017183 and DPC Instrument Systems Division Registration Number is 2247117

**Substantially Equivalent Predicate Device:** IMMULITE (K905215)

**Description of Device:** IMMULITE 1000 Automated Immunoassay Analyzer

**Intended Use of the Device:**

These modifications do not change the indications for use, nor the intended use from the IMMULITE to the IMMULITE 1000. The DPC IMMULITE 1000 is an automated immunoassay system intended to assay the same broad range of analytes in patient samples as does IMMULITE. The intent of the system is to impart the same automation to the array of immunoassays in the same hospital and commercial laboratory settings as IMMULITE. The system is intended to produce safe and effective performance when used by medical laboratory personnel as is the IMMULITE predicate system.

**Product Description:**

The DPC IMMULITE 1000 product is essentially an upgrade of the current IMMULITE system. All of the current functionality will be retained; however, the system will be enhanced with regard to the user interface, casework, and system footprint. The operating system will be changed to a Windows 2000 environment. In addition, the system will be remodeled to give the IMMULITE a more "modern" look and feel to be part of the "IMMULITE Family". Finally, the total system footprint will be decreased by such mechanisms as integrating the PC into the architecture of the system and provide a defined area for storing bulk materials (i.e., waste, water, and, probe wash).

**Technology:**

The IMMULITE 1000 uses ¼ inch polystyrene antibody coated beads and assay specific antibody or antigen labeled with alkaline phosphatase. The chemiluminescent detection system is a phosphate ester stabilized dioxetane. Cleavage of the phosphate ester by alkaline phosphatase results in the decomposition of the dioxetane and the emission of photons, which are quantified by a luminometer and are proportional to the quantity of analyte present.

**Conclusion:**

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the IMMULITE 1000 Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 21 2002

Edward M. Levine, Ph.D.
Director, Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597

Re: k022603
Trade/Device Name: IMMULITE® 1000 Automated Immunoassay Analyzer
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW; JJE; DHA; LGC; DCN; LPS; JMF; CFP; DHB; CEP; LAF; DDR; LTK; JFH; DLZ; DIP; JLS; CFT; LTJ; JMM; JLW; LFX; CEE; KLS; MSW; JHR; CDP; KLI; CDZ; LGD; MMI; JHX; CGI; LEG; CDD CKG; LOJ; DFJ; DGO; DKZ; JZO; MOI; LDJ; KLT; DHX; LFZ; DIO; CGR; JKD; JKC; LFM; KXT; GGT; CHP; JMG; CGN; CEC; CGJ; CFL; LYR; JZG
Dated: August 5, 2002
Received: August 6, 2002

Dear Dr. Levine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022603
Device Name: IMMULITE® 1000 Automated Immunoassay Analyzer

Indications For Use: The DPC IMMULITE 1000 is an automated immunoassay system intended to assay the same broad range of analytes in patient samples as does IMMULITE. The intent of the system is to impart the same automation to the array of immunoassays in the same hospital and commercial laboratory settings as IMMULITE. The system is intended to produce safe and effective performance when used by medical laboratory personnel as is the IMMULITE predicate system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leon Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022603

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)